REMARKS

Amendment to the Specification

The Specification has been amended to provide the trademark RENAGEL® in all capital letters. No new matter has been added.

Specification

The Specification has been amended to capitalize the trademark RENAGEL®, as requested by the Examiner. No other occurrences of this trademark appear in the present application.

Priority Claim Under 35 U.S.C. 119(e)

Applicants once again note that priority is claimed to U.S. Provisional Application No. 60/160,258 filed October 19, 1999 and U.S. Provisional Application No. 60/174,227, filed January 3, 2000. The priority claims have not been acknowledged in an Office Action. The Examiner is respectfully requested to acknowledge the priority claims in the next Office Action.

Rejection of Claims 2-22 Under 35 U.S.C. § 103(a)

Claims 2-22 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,264,937 (hereinafter referred to as "the '937 Patent") in view of U.S. Patent No. 4,302,440 (hereinafter "the '440 Patent"). The Examiner stated that it would have been obvious to one of ordinary skill in the art to use the aqueous coating taught by the '440 Patent with the tablet of the '937 Patent. For the reasons set forth below, this rejection is respectfully traversed.

Claims 2-18 and 22

Claims 2-18 and 22 each require that the claimed tablet have a core comprising at least about 95% by weight of an aliphatic amine polymer such as unsubstituted or N-substituted poly(allylamine), poly(diallylamine) and poly(vinylamine). The cited passage of the '937 Patent, column 11, lines 21-24, states that fat-binding polymers (including poly(allylamine), poly(diallylamine) and poly(vinylamine)) can be formulated using conventional inert pharmaceutical adjuvant materials into oral dosage form such as a tablet. The '937 Patent does

not, however, disclose the weight ratio of the aliphatic amine polymer in the tablet core. In particular, the '937 Patent does not disclose or suggest that it is possible for the tablet core to contain at least about 95% of an aliphatic amine polymer or how one would prepare such a tablet core.

The scope of the disclosure regarding tableting of aliphatic amine polymers in the '937 Patent is virtually identical to that of U.S. Patent No. 5,496,545 (hereinafter referred to as "the '545 Patent; see Col. 17, lines 20-47). In both patents, it is stated that aliphatic amine polymers can be tableted. However, neither patent teaches the proportion of aliphatic amine polymer in a tablet core or a method of preparing a tablet core with greater than about 95% by weight of an aliphatic amine polymer. In the instant Office Action, the Examiner has withdrawn an obviousness rejection over the '545 Patent in view of the '440 Patent. It is not clear to Applicants what additional disclosure is present in the '937 Patent that merits a new rejection under 35 U.S.C. § 103(a). The Examiner is respectfully requested to clarify the basis on which the new rejection over the '937 Patent was introduced.

Applicants note that it was unexpected that tableting a composition having at least about 95% poly(allylamine) would be successful. The instant specification at page 1, line 19 to page 2, line 8 teaches that formulation of a polymer into a tablet is generally not possible without the addition of significant quantities of other materials that assist in the tableting process (e.g., inert pharmaceutical adjuvant materials). Thus, there was no reasonable expectation that a tablet core containing at least 95% by weight of poly(allylamine), and thus devoid of significant quantities of adjuvant materials, could be made.

The teachings of the '440 Patent are not considered to be relevant to the instant claims or to overcome the deficiencies of the '937 Patent. There is no teaching or suggestion in the '440 Patent that a coating appropriate for aspirin, a small molecule, would also be appropriate for a polymer. In fact, one skilled in the art would not expect that it would be possible to coat an aliphatic amine polymer-coated tablet in the manner in which aspirin tablets are coated per the '440 Patent. Coatings are typically applied to a tablet using a water-based solvent (see Col. 3, lines 14-17 of the '440 Patent). It is expected that the water in the coating would cause the aliphatic amine polymer-containing tablet to swell, consequently degrading the physical and mechanical stability of the tablet. In addition, the '440 Patent does not teach the formulation of a

tablet core comprising aliphatic amine polymers. Thus, the '440 Patent does not overcome the deficiencies of the '937 Patent.

In summary, the combined disclosures of the '937 Patent and the '440 Patent neither teach nor suggest a tablet having a tablet core and a coating, where the tablet core comprises at least 95% of an aliphatic amine polymer. Therefore, Claims 2-18 are not obvious over the '937 Patent and the '440 Patent, and the rejection should be withdrawn.

Claims 19-21

Claims 19-21 are directed to a compressed tablet comprising a pharmaceutically active agent ***and*** an effective disintegrating amount of polyallylamine or a salt thereof. Thus, the subject matter of Claims 19-21 differ from the '937 Patent in that polyallylamine is present in addition to the pharmaceutically active agent. Polyallylamine is present in a tablet ***in addition to*** the pharmaceutically active agent because of Applicants' unexpected discovery that polyallylamine enhances the rate of tablet disintegration under conditions of use. Thus, the claimed tablets have the unexpected advantage of providing for more rapid drug release. The polyallylamine is generally not serving as a pharmaceutically active agent in these pharmaceutical compositions.

The '937 Patent does not disclose a compressed tablet comprising a pharmaceutically active agent and polyallylamine as a disintegrant. Moreover, the '937 Patent does not teach that polyallylamine or a salt thereof can be used as a disintegrating agent in compressed tablets and therefore does not teach how to achieve more rapid drug release from the tablet.

The teachings of the '440 Patent are not considered to be relevant to the instant claims or to overcome the deficiencies of the '937 Patent. The '440 Patent provides no teachings regarding polyallylamine, let alone a compressed tablet containing a pharmaceutically active agent and polyallylamine as a disintegrant. It also does not teach how to achieve more rapid release of a pharmaceutically active agent from a tablet by employing polyallylamine as a disintegrant, as set forth in Claims 19-21. Thus, the '440 Patent cannot remedy the deficiencies of the '937 Patent.

For these reasons, the disclosures of the '937 Patent and the '440 Patent cannot be combined to teach a compressed tablet comprising a pharmaceutically active agent and an

effective disintegrating amount of polyallylamine. Therefore, Claims 19-21 are not obvious over the '937 Patent in view of the '440 Patent. Withdrawal of the rejection is respectfully requested.

Conclusion

The above discussions demonstrate that the cited references, separately or in combination, do not teach or suggest either (i) a tablet comprising a tablet core containing at least about 95% by weight of an aliphatic amine polymer and a coating thereof or (ii) a compressed tablet comprising an effective disintegrating amount of polyallylamine and a pharmaceutically active agent. Thus, the instant claims are not obvious over the cited references. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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